EXHIBIT 15

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA

BENJAMIN COKER, *et al*. Plaintiffs, v. LLOYD AUSTIN, III, in his official capacity as Secretary of Defense, *et al*., Defendants.	)	Civil Action No. 3:21-cv-01211-AW-HTC

DECLARATION OF COLONEL TONYA RANS

I, Colonel Tonya Rans, hereby state and declare as follows:

1. I am currently employed by the U.S. Air Force as the Chief, Immunization Healthcare Division, Defense Health Agency – Public Health Directorate, located in Falls Church, Virginia. I have held the position since June 2017. I am a medical doctor and have been board certified in Allergy/Immunology since 2008 and was a board-certified Pediatrician from 2001-2015.

2. In my current role, my responsibilities include directing a responsive, evidence-based, patient-centered organization promoting optimal immunization healthcare for all Department of Defense (DoD) beneficiaries and those authorized to receive immunizations from DoD. This includes assisting in policy development, providing implementation guidance and education, and engaging in clinical studies through clinical collaboration. The Defense Health Agency-Immunization Healthcare Division (DHA-IHD) routinely engages with the medical representatives from the military departments, U.S. Coast Guard, Joint Staff, Combatant

Commands, and others to develop standardized immunization implementation guidance in accordance with published policy for consistency across DoD where possible.

3. This declaration is based on my personal knowledge, as well as information made available to me during the routine execution of my official duties.

4. On December 11, 2020, the U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for Pfizer-BioNTech's COVID-19 vaccine for the prevention of COVID-19 disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. On August 23, 2021, the FDA approved the biologics license application (BLA) for Pfizer-BioNTech's COVID-19 vaccine, marketed as Comirnaty, for active immunization to prevent COVID-19 in individuals 16 years of age and older. The FDA states that "The FDA-approved Comirnaty (COVID-19 Vaccine, mRNA) and the FDA-emergency use authorized Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older, when prepared according to their respective instructions for use, can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. Therefore, providers can use doses distributed under EUA to administer the vaccination series as if the doses were the licensed vaccine. For purposes of administration, doses distributed under the EUA are interchangeable with the licensed doses."[1]

5. On September 14, 2021, the Assistant Secretary of Defense for Health Affairs issued guidance, consistent with this FDA guidance, stating the Pfizer-BioNTech EUA and Comirnaty vaccines have the same formulation and are "interchangeable," and that DoD healthcare providers should "use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine" for the purpose of vaccinating service members in accordance

[1] https://www.fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna, last accessed May 18, 2022.

with the Secretary of Defense's August 24, 2021 mandatory vaccination memorandum. Exhibit A.[2]

6. In addition, the FDA determined that some lots of the vaccine produced at facilities and released in accordance with Pfizer-BioNTech's licensed Comirnaty were manufactured in compliance with the BLA. Pfizer-BioNTech provided a memo in their shipping containers which referred to a link where lot numbers for these Pfizer-BioNTech BLA-compliant vials could be located. The memo and lot information are publically accessible, though the link has been updated from Pfizer BioNTech's memo as additional COVID-19 vaccines have been added to their portfolio.[3]

7. To date, DoD has received approximately 430,000 doses of Pfizer-BioNTech BLA-compliant, EUA-labeled COVID-19 vaccine doses and continues to use them. Exhibit C.[4]

8. As of May 20, 2022, DoD has 872 vials of BLA-compliant vaccine, equaling approximately 5,200 doses. The latest vial expiration date is currently September 30, 2022. Exhibit D.

9. In accordance with CDC's Advisory Committee on Immunization Practices General Best Practice Guidelines for Immunizations, the Department of Defense tracks the lot numbers of all vaccines[5]. The Department tracks the location of the lots from the time they are initially received through when they are administered to patients or discarded due to expiration

[2] On January 31, 2022, FDA approved the BLA for the SPIKEVAX COVID-19 mRNA vaccine, made by ModernaTX, Inc. Following subsequent FDA guidance, DoD issued a separate interchangeability memorandum for SPIKEVAX, consistent with the department's earlier interchangeability guidance for Comirnaty. Exhibit B.

[3] https://www.cvdvaccine-us.com/16-up-yearsold/resources, last accessed May 18, 2022.

[4] The chart attached at Exhibit C is based on information in DoD records and is intended to reflect the shipment date, numbers, and lot numbers of BLA-manufactured doses. Redistributed doses are included in a separate column.

[5] https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html, last accessed May 18, 2022.

and lot numbers are documented in beneficiary immunization print outs. Exhibit E reflects the current location of the 872 vials in DoD's possession as of May 20, 2022. These vials can be redistributed to other locations.

10. The interchangeability guidance described in paragraphs 4-5 is not limited to the BLA-compliant vials described in paragraphs 6-8; rather, in accordance with FDA guidance, DoD may also use Pfizer-BioNTech doses distributed under the EUA "as if the doses were the licensed vaccine."[6]

11. As of May 20, 2022, Pfizer-BioNTech's Comirnaty-labeled vaccine is now available for DoD ordering.[7] Delivery to immunization sites typically occurs within 1-2 weeks once order is placed by the MTF. Given ample USG supply of Comirnaty-labeled product, DoD does not anticipate needing to initially restrict this product.

12. Complying with lawful orders is the responsibility of the individual service member. Failure to comply with a lawful order may result in adverse administrative or judicial consequences. To ease the burden on service members complying with this lawful order, the Secretary of Defense's August 24, 2021 mandatory vaccination memorandum provides multiple ways to become compliant. Service members can meet the terms of this mandate by receiving a FDA-licensed or Emergency Use Authorization issued COVID-19 vaccine or a World Health Organization Emergency Use Listing vaccine. Likewise, service members are not required to be vaccinated by military providers, but may choose to get vaccinated in the civilian sector, so long as they provide proof of vaccination for documentation. Exhibit F.

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[6] https://www.fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna, last accessed May 18, 2022.

[7] Prior to this, DoD was not in possession of Comirnaty-labeled vaccine.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on June 1, 2022, in Falls Church, Virginia

Tonya S. Rans
Colonel, Medical Corps, U.S. Air Force
Director, Immunization Healthcare Division
Public Health Directorate
Falls Church, Virginia